

# **EXHIBIT B**

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## Abstract

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## Local foreign-body reaction to commercial biodegradable implants: an in vivo animal study.

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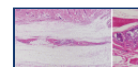
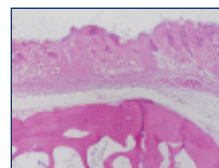
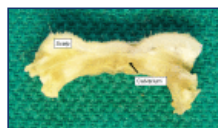
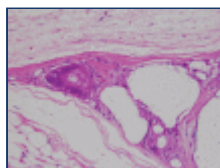
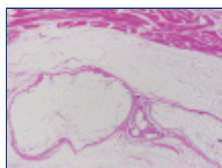
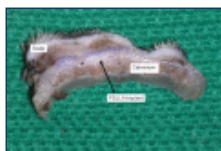
### Author information

### Abstract

Biodegradable plates have been used extensively in fracture fixation since the 1960s. They rarely cause stress-protection atrophy or problems requiring secondary plate removal, common complications seen with metallic plates. However, aseptic foreign-body reactions have been reported, sometimes years after the original implantation. Both inadequate polymer degradation and debris accumulation have been implicated as causes. The current generation of commercial biodegradable plates is formulated to minimize this complication by altering the ratio of polylactic and polyglycolic acids. This in vivo study compares the degree of local foreign-body reaction of two commercially available resorbable plates in rabbits. Two types of biodegradable plates were examined: poly(D/L)lactide acid (PDLLA) and polylactide-co-glycolide acid (PLGA). Each plate was placed into a periosteal pericalvarial pocket created beneath the anterior or posterior scalp of a rabbit. Humane killing occurred at 3, 6, and 12 months postoperatively. Foreign-body reaction was evaluated histologically. The PDLLA plates demonstrated marked local foreign-body reactions within the implant capsule as early as 3 months after implantation, with presence of inflammatory cells and granulomatous giant cells in close association with the implant material. All local foreign-body reactions were subclinical with no corresponding tissue swelling requiring drainage. PLGA plates did not demonstrate any signs of inflammatory reactions. In addition, the PLGA plates did not appear to resorb or integrate at 12 months. Neither PDLLA nor PLGA plates demonstrated inflammation of the soft tissue or adjacent bone outside the implant capsule. In our study, the PDLLA plates demonstrated histological evidence of foreign-body reaction that is confined within the implant capsule, which was not seen with the PLGA plates. This finding may be attributable to the lack of significant resorption seen in the PLGA plates. Both PDLLA and PLGA plates were biocompatible with the rabbit tissue environment and should be considered for continued use in craniofacial, maxillofacial, and orthopedic reconstruction.

**KEYWORDS:** local foreign-body reaction; local inflammatory reaction; resorbable plates; sterile abscess

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